



K960551

Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster, Texas 77598-4217
Tel 713.332.9678
Fax 713.554.4220
Customer Assistance Center
Tel 800.231.7978
Fax 713.338.1899

SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 10-1900 hGH ELISA Kit.
Classification Name: Enzyme-Linked Immunosorbent Assay, hGH.
Analyte Name: Human Growth Hormone.
Regulatory Class: I

Submitter: John Willis
Diagnostic Systems Laboratories, Inc.
445 Medical Center Blvd.
Webster, Texas 77598
Phone: (713) 332-9678

Date: February 7, 1996

The DSL Active hGH ELISA Kit was developed for the quantitative measurement of human growth hormone in human serum. Mouse monoclonal antibody "capture antibody" is immobilized to the inner surface of microtiter plate wells. Growth hormone in the standards or serum samples is "sandwiched" between the capture antibody and the anti-hGH monoclonal antibody conjugated to horseradish peroxidase enzyme.

The measurement of growth hormone in serum is used as a diagnostic aid in the evaluation of hGH deficiency disorders or acromegaly.

The DSL hGH ELISA is substantially equivalent to the Nichols Institute hGH IRMA. These kits have the same intended use.

To demonstrate substantial equivalence between the two assays, 41 patient samples were collected and assayed simultaneously by both methods. Samples were chosen with low medium and high levels of hGH. Linear regression analysis of the results obtained for the comparison yield the following results: $Y = 1.06x + 0.25$ with a correlation coefficient of 0.99.

RECEIVED
8 FEB 50 09 46
FBI/DOJ/DOH